REMARKS:

This application has been carefully studied and amended in view of the Office Action dated January 3, 2006. Reconsideration of that action is requested in view of the following.

Claim 7 has been amended to delete the redundancy pointed out by Examiner Arnold.

Claim 1 has been replaced by Claim 13. Claim 13 is now in the form of a method claim for manufacturing an adjuvant which comprises xenon in the form of xenon or a xenon-containing gas. Accordingly, claim 13 should comply with 35 USC §101 in that by being a method claim it does not read upon a natural product.

Reconsideration is requested of the rejection of claims 8-9 under 35 USC §101 and 112. Claim 8 has been replaced by claim 14 which is also a method claim rather than a "use" claim. The method includes reciting how the adjuvant is made so that it is capable of having the uses defined in claim 14.

Reconsideration is requested of the rejection of the various claims over the later discussed different items of prior art relied upon in the Office Action. There are three independent claims, namely, claims 6, 13 and 14. Each of these claims is directed to aspects of the invention regarding an adjuvant which comprises some form of xenon. It is emphasized that an adjuvant is not a medicament. An adjuvant is known to one of ordinary skill in the art as something that helps or facilitates such as to enhance the effectiveness of a medical treatment. As stated at lines 23-24 on page 1 of the specification "Means assisting the effect of a medicament are referred to in medicine as adjuvant". Claim 6 has been amended to make clear that the adjuvant functions to assist the medicament. Support for claim 6 is found on page 1, last line to page 2, line 5 of the specification. A common thread in the various references which had been relied upon for rejecting the claims is that the references were concerned more with a medicament than with an adjuvant. Examiner Arnold should appreciate, however, that an

adjuvant is not an active agent, but would merely facilitate the action of physiologically active agents, that is a medicament.

FISHMAN REFERENCE

Reconsideration is respectfully requested of the rejection of the claims as anticipated by Fishman (U.S. 5,228,434).

The technical field of Fishman is related to anesthesia wherein a gas is breathed by the patient to achieve the desired effect. (Column 1, lines 9, 10). Moreover, the Fishman reference is directed to a method of anesthetizing a patient by providing a combination consisting of three gases, which are xenon, oxygen and helium, as a medicament for the treatment of a patient i.e. to anesthetize him. (Column 2, lines 16-22). It is disclosed that oxygen serves to provide life and that xenon acts as the anesthetizing agent (Column 2, lines 61 — 63). This indicates that xenon and oxygen are acting as the active ingredients in this mixture and that xenon is not acting as an adjuvant. It is further disclosed that helium reduces the density of the total anesthetic gas mixture delivered to the patent and, in addition, reduces respiratory work and/or supports the more even distribution of the anesthetic xenon gas within the lungs (column 3, lines 8 — 12) or that helium improves the distribution of the anesthetic gas mixture (composed of xenon plus helium) in the lungs, respectively (column 5, lines 3,4).

This unambiguously proves and are striking arguments that xenon (and oxygen) is the active ingredient and that it is the helium gas that may be considered as the component of the gas mixture acting as an adjuvant in Fishman. The fact that only xenon is the sole and true active (anesthetizing) agent is farther supported by the disclosure that "this ... makes xenon a rapidly reversible anesthetic." (column 4, lines 18—22). In this context the use of methyl-atropine bromide as described in column *5,* lines 10— 15 means the use of a second active medicament together with the third active medicament thiopentone. Nothing can be taken from this disclosure that would make the present invention obvious, let alone that would anticipate the present invention but just the contrary is the case.

Finally, as noted above reference should be made to page 1, lines 23-24, of the specification where it is defined that "Means assisting the effect of a medicament are referred to in medicine as adjuvant." (emphasis added) Therefore, there is a clear distinction between a medicament per se and an adjuvant.

From the above it is clear that the Fishman reference significantly differs from the subject matter of the present invention and unambiguously teaches away from the present invention. Fishman teaches to use xenon as an active agent for specific medical purpose and does not disclose an adjuvant comprising xenon or a xenon-containing gas.

PETZELT REFERENCE

Reconsideration is respectfully requested of the rejection of claims as anticipated by Petzelt, et al. (WO 00/53192)

As regards Petzelt et al. this reference deals with preparations containing xenon for treating neurointoxications and their use in treating same (page 4, penultimate and last paragraph, page *5,* paragraph l, claims 1, 7,16) and the therapeutic use of xenon, especially for treating neurointoxications in therapeutically useful concentrations.

The Petzelt et al. reference does not go beyond the Fishman reference as the Petzelt reference also discloses a medicament containing an active agent for a further medical use. This is proved by the statement that "xenon enables a fully new field of application for this noble gas, which has been used increasingly as inhalation anesthetic agent" (page 5, last paragraph). This statement might be unequivocally referred to the Fishman reference. In this context reference is made to page 11, last paragraph, were it is stated that xenon can be used in defined concentrations in a therapeutically useful manner in all pathologic conditions characterized by a disorder.

In addition, all Examples 1 and 2 are carried out under in vitro conditions using isolated cells. However, a person skilled in the art would by no means get any incentive to the use of a physiologically active substance from in vitro experiments for the purpose to use it as an adjuvant. This is because isolated cells do not possess vessels or a bloodstream within which an adjuvant may facilitate the transport of an active agent.

LECOURT REFERENCE

Reconsideration is respectfully requested of the rejection of the claims as anticipated by Lecourt, et al. (U.S. 2002/0033174).

The Lecourt et al. reference pertains to the use of a gas and of inhalable aerosol medicament for the treatment or prevention of pain. Specifically, Lecourt discloses the administration of a medicament by the inhalation route in the form of an aerosol (page 2, [0024)) by using a gas in combination with at least one active agent (page 2, [0028)).

The gas is chosen from among those elements and compounds that are normally gaseous under common air pressure and temperature. These include helium, oxygen, nitrogen, xenon, hydrogen, carbon monoxide, carbon dioxide, argon, krypton, nitrogen monoxide, nitrogen protoxide, carbonated hydrocarbons, fluorocarbons and mixtures of several of this gases (page 2, [0033], [0043]). The fluorocarbons alone would represent a big group of *gases* with quite different chemical constitution, let alone all gases mentioned in above. That means that all possible kinds of gases commonly available or accessible under normal environmental conditions are suitable without any preference and without any limitation.

Accordingly, without any knowledge of the present invention (hindsight) a person skilled in the art would not get any hint from the Lecourt et al. reference to choose one specific gas for the claimed use.

The Examiner's assertion as to the potential synergistic effect of xenon and steroidal anti-inflammatory active principles is taken out of context (page 6, penultimate paragraph, with reference to page 3 *[0059]).*

As with the Petzelt et al. and Fishman et al. references, the Lecourt et al. reference teaches that "some gases with therapeutic effects can be used ... by virtue of a synergistic action of the [therapeutically active] gas and said active principles (page 3, [*0058],* emphasis and bracket added).

By the way, the choice of a combination of xenon and a steroidal anti-inflammatory principle as depicted in the Table under paragraph *[0059]* is not very surprising since it is known that xenon has an anti-inflammatory activity (Georgieff et al., US 6,197,323, column *9,* line 38, claim *5,* also cited by the Examiner on page 7 of the Office Action, see below). Since US 6,197,323 was published on March 06, 2001, it is prior art to the Lecourt et al. reference. However, this has nothing to do with the present invention but, again, teaches away from it. Again, the present invention as defined in the pending claims, does not address xenon as an active principle.

Moreover, the physical function of the gas is to nebulize or to disperse the active principles before administering it to the patient via an aerosol dispenser (page 3, [0047], *[0050]* - *[0053],* [0056]).

Reconsideration is respectfully requested of the rejection of various claims as anticipated by Georgieff et al. (U.S. 6,197,323).

The Georgieff et al. reference describes the therapeutical use of gases, in particular of a mixture of xenon and krypton (column 3, lines 31 —33) to provide liquid preparations (column 4, lines 24 — 27) for the treatment of disorders for which agents having analgesic or anti-inflammatory activities are needed.

As with the other references, nothing can be taken from the Georgieff reference that would anticipate any of the claims or would them make obvious.

FRANKS REFERENCE

Reconsideration is respectfully requested of the rejection of various claims as anticipated by Franks et al. (WO 00/76545).

The same arguments mentioned above can be applied analogously to Franks et al. Franks et al. provide a pharmaceutical comprising a N-methyl-D-aspartate (NMDA) antagonist and an alpha-2 adrenergic agonist. The NMDA antagonist can be chosen from different compounds but it is preferably xenon (page 4, lines 15 to 22). Franks et al. discloses that xenon is an anesthetically active agent (page 4, lines 24, 25).

Thus, the embodiment of the Franks et al. reference, which was filed on June 9, 2000, is identical with the same embodiment as published in the Fishman et al. reference on July 20, 1993.

Therefore, Franks et al. do not go beyond the Fishman reference as both references disclose xenon as a medicament for use as an anesthetic.

All in all, and having now discussed the state of the art cited by the Examiner it seems to be very surprising that a substance from which it is only known that it is the active agent in the treatment of adverse conditions and *several* diseases, that this same substance is also suitable as a therapeutically inactive adjuvant.

This also clearly supports the non-obviousness of the present invention.

Since the references does not teach the invention as claimed and since the references do not provide any motivation or incentive to manufacture an adjuvant as claimed in the pending

claims, the claims are not anticipated by the cited prior art, are not obvious and should be allowed.

DOUBLE PATENTING

It is noted that the double patenting rejection is a "provisional" rejection in that claims have not been allowed in copending application S.N. 10/380,869 or in copending application S.N. 10/517,722 or in copending application S.N. 10/517,223". Upon the allowance of such claims applicants will file an appropriate terminal disclaimer so as to address the double patenting rejection.

In view of the above remarks and amendments this application should be passed to issue.

Dated: 3-30-06

Respectfully submitted,

By Harold Pezzner

Harold Pezzner
Registration No.: 22,112
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
P.O. Box 2207
Wilmington, 19899
(302) 658-9141
(302) 658-5614 (Fax)
Attorney for Applicant

452752